PHASE I/II TRIAL OF ANTIGEN-SPECIFIC IMMUNOTHERAPY IN MUC-1 POSITIVE PATIENTS WITH ADVANCED NON-SMALL CELL LUNG CANCER USING VACCINIA-VIRUS-MUC1-IL2 (TG 1031)

1. Introduction

TG 1031, an attenuated recombinant vaccinia virus containing sequences coding for the human MUC-1, and Interleukin 2 (IL-2) genes, has been designed for use in human clinical applications, especially in oncology. The vector, vaccinia virus, has been used extensively to vaccinate against smallpox and the virus is known to be highly immunogenic. The second component of the product, MUC1, is a mucin producing gene which is overexpressed in a variety of adenocarcinomas. The third component, the IL2 gene, produces local generation of interleukin 2 and stimulates cytotoxic T lymphocyte production. This virus produces an antitumor effect, as observed in many experiments on animals. TG 1031 has been tested in a phase I clinical trial, at Institute Curie (Paris, France), in metastatic breast cancer which is discussed in section 1.4 below, and is currently being tested in phase II trials in breast and prostate cancer.